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10/543,001

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EXAMINER

BRUTUS, JOEL F

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

12/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/543,001 | <b>Applicant(s)</b><br>SARDAR ET AL. |  |
|                              | <b>Examiner</b><br>JOEL F. BRUTUS    | <b>Art Unit</b><br>3768              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/13/2007</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Specification***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 7-13, 15-19, 22-35, 38-40, and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Hay et al (US Pat: 5,632,282).

Regarding claims 1-5, 7-13, 15-19, 22-35, 38-40, and 42-43, Dreher et al teaches means and method for determining thickness of the nerve fiber layer of the fundus of the eye by measuring the polarization shift of the reflected probing light that is pertinent to the claimed invention. Dreher et al further teaches an array of polarizers, a micro computer, a diagnostic beam, corneal polarization compensator, beam splitter, ADC [see fig 3]; the system uses a laser diode to provide a beam of light that is focus by a lens [see column 4 lines 40-44]; a linear polarizer, a laser, laser diagnostic beam, array of polarizers, computer [see column 6 lines 30-50]; a polarization sensitive detection means [see column 2 lines 60-64]; measuring polarization shift [see column 4 lines 33-40]. Dreher et al also teaches an ellipsometer to capture and analyze polarization information [see column 6 lines 6-9]; a detector that measures absolute intensity of returned diagnostic beam [see column 7 lines 65-67, column 8 lines 1-5]; diagnose early glaucoma and eye diseases [see column 8 lines 60-63], a variable retarder to adjust to

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maximize the intensity of the light in the polarized state [see column 5 lines 50-53]; incident diagnostic beam could be scanned by a scanning unit [see column 6 lines 65-68]; choroid (or choroidal tissue) [see column 3 lines 55-56]

Dreher et al further discloses the technique used to diagnose diseases of the eye. The retinal nerve fiber layer comprises an array of radially arranged nerve fibers. This array acts as a linear birefringent medium. It is illuminated with linearly polarized light, and the reflected from the ocular fundus is passed through an analyzer [see column 8 lines 16-17] with an orthogonal polarized filter to a photo detector or collector [see column 8 lines 17-19]. There will darkness along the polarization axes of both the incident light beam and the analyzer filter. The bright portion of the cross gives an accurate indication of the thickness of the nerve fiber layer at these points as substantial change in the polarization caused by substantial nerve fiber layer thickness will shift the polarization of the light adequately to pass through the analyzer polarization filter [see column 8 lines 20-31]. A second photo detector is used to measure the total amount of reflected intensity of the return diagnostic beam at the corresponding points on the fundus. By normalizing the intensity values obtained with the first photo detector with the corresponding values of the second detector, absolute changes in the state of polarization of the return diagnostic beam are calculated [see column 8 lines 43-50]; the polarization technique disclosed make a substantial contribution to the ability to diagnose the interior eye, especially early diagnosis of glaucoma [see column 8 lines 60-63].

Dreher et al doesn't teach a specific ocular disease, a tissue sample holder.

However, Hay et al teaches a method for diagnosing a plurality of disorders of optical media of the eyes is disclosed. A beam light is directed into eyes of a subject, and the retinal reflection, or reflex, emerging from the pupil is detected and analyzed [see abstract]. In some instances intensity levels of the reflex are compared against a reference reflex representative of normal eye to isolate abnormal ocular conditions [see abstract]. Hay et al teaches a device to detect ocular diseases, macular disease such as degenerative conditions, infection and tumors (cancer) [see column 6 lines 42-50]; the device comprises a chinrest to position the eye within the area of the beam light [see column 8 lines 18-24] and stabilizing bar to stabilize the head and thus the eye [see column 8 lines 22-24].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of providing an efficient and reliable diagnosis of the eye. Using the sample holder to stabilize the desired examined are as to precisely and accurately focus the laser beam into the eye.

4. Claims 20-21, 36-37, 41, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Hay et al (US Pat: 5,632,282) as applied to claim 1 above, and further in view of Trachtman (US Pat: 5,002,384).

Regarding claims 20-21, 36-37, 41, and 44, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach photodiode, digital meter.

However, Trachtman teaches an apparatus for monitoring and training eye position under clinical conditions. Sensors means can be photodiodes [see column 16 lines 41-56]; digital meter [see column 19 lines 25-35, 45-55]; a small computer [see column 19 lines 54-55]; sample holder [see column 19 lines 8-20].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of having the capability of converting light into either current or voltage, depending upon the mode of operation; and using the digital meter for higher accuracy, efficacy and greater precision.

5. Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Hay et al (US Pat: 5,632,282) as applied to claim 1 above, and further in view of Larrick et al (US Pat: 5,670,151) or Glaser et al (US Pat: 5,767,079).

Regarding claims 6 and 14, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach diagnosing diabetes retinopathy.

However, Larrick et al teaches a form of disorder of the eye is diabetes retinopathy [see column 2 lines 13-20].

Glaser et al teaches method for treating ophthalmic disorders like retinal disorders, choroidal tissue, macular degeneration, neovascularization, diabetic retinopathy [see column 1 lines 33-36].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of providing diagnosis to evaluate the extent or spread of the disease as to prescribe the best possible treatment; thus prevent any further eye problems or blindness.

### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768